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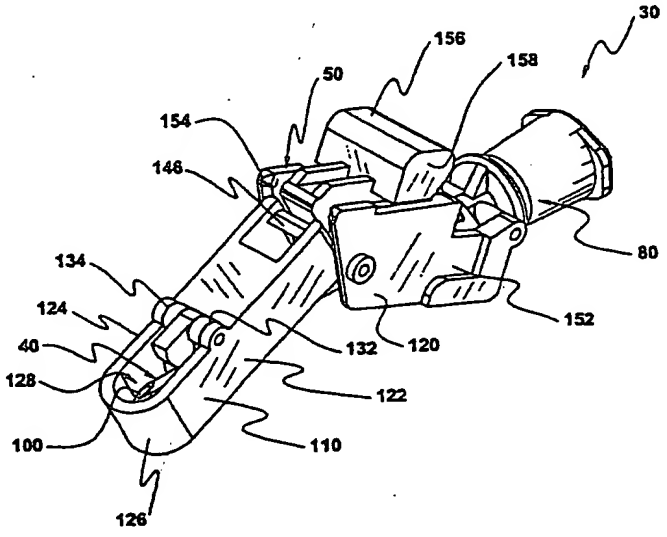
(54) Title: REACCESSIBLE MEDICAL NEEDLE SAFETY DEVICES AND METHODS



(57) Abstract: A retractable and extendable medical needle protective shield (50, 50') which provides for accessing and reaccessing a medical needle (40) and associated sharpened needle tip (100) and recovering the needle (40) and tip (100) for safety between accesses. The shield (50, 50') includes a needle guide (130, 138) which assures the needle tip (100) is untouched by any part of the shield (50, 50') as the shield (50, 50') is displaced to cover and uncover the needle (40). A releasible latch (148, 162) is provided to guard against inadvertent removal of the protective shield (50, 50') between accesses. An unreleasible latch (182, 190) is also provided to secure the shield (50, 50') relative to the latch (182, 190) preparatory to final disposal.

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REACCESSIBLE MEDICAL NEEDLE SAFETY DEVICES AND METHODS

FIELD OF THE INVENTION

This invention relates generally to safety devices for hollow bore medical needles and particularly to syringe needle devices which employ protective needle shields or sheaths for securely shielding sharp needle tips, both before and after being used in a medical procedure. This invention more particularly relates to removable medical needle shields, sheaths or shrouds, which may be used as removable and replaceable protective needle covers. Consistent with such uses, the medical needle may be accessed, covered and reaccessed repeatedly for such purposes as protecting a sharpened needle tip in transit before use, ad interim after a preliminary use, such as filling a syringe with a medication, and being displaced to a safety, needle-covering position after a medical procedure is completed.

BACKGROUND OF THE INVENTION

Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Ever increasing attention is being paid to needle stick problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne diseases.

Procedures involving removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle apparatus with the other hand. It is common practice for an attending technician to give higher priority to care for the wound than is given to disposal of a needle. In the case of common non-safety devices, such priority either requires the convenience of an available sharps container within ready reach or another means for safe disposal without leaving the patient's side. Providing adequate care, with accompanying safety procedures, is often compounded by the patient's physical condition and mental state (e.g., in burn units and psychiatric wards). Under such conditions, it is often difficult, if not impossible, to take the appropriate action to properly dispose of a used, exposed needle while caring for a patient. The common

practice of filling syringes with medication in one area and then transporting an uncapped needle to a patient area provides a significant opportunity for accidental needle sticks. Recapping a needle is currently discouraged in U.S. medical practice due to the dangers of accidental needle sticks associated with recapping.

The widespread knowledge and history associated with needle care and disposal problems have resulted in the numerous devices for preventing accidental needle sticks. Current devices for shielding syringe needles often require two hands, and with some devices the safety status of needle shields are not readily apparent.

There is often a need to use syringe needles a plurality of times. When an intramuscular injection is made, it is common practice to draw the contents from a drug vial into a syringe and then inject the contents into a patient. It is desirable to use the same needle for penetrating a membrane on the drug vial and then for injecting the patient. However, the site where contents are drawn from the drug vial may be some distance from a site where the patient is to be injected, which may result in a technician's recapping the needle for transport to the patient. Equally as concerning is another practice of carrying the needle unprotected. Some currently available safety devices permit covering and reaccessing a needle. However, factors such as those disclosed above have limited acceptance of these safety devices.

There remains a need to provide a more satisfactory solution to a needle safety device which is reaccessible for multiple uses.

SUMMARY OF THE INVENTION

In brief summary, the novel invention disclosed herein dramatically diminishes known major problems resulting from injury-related needle sticks which occur when needle tips are bared as medical needles are withdrawn from a patient at the end of a needle insertion procedure. The present invention permits access to a medical needle in several steps in medical procedure, while being able to return the needle to the safety of a covering enclosure between the steps.

The present invention employs a protective needle shield which is displaceable to cover and protect a needle tip and which is further displaceable to bare the needle and

tip a plurality of times for use throughout a medical procedure. Moreover, the needle tip is untouched by the shield in addition to being protectively covered.

In the present invention, a shield is disposed about a needle and tip to provide protection. A temporary, releasible latch is provided which may be disengaged to permit the shield to refold and, thereby, permit reaccess to the needle for a subsequent medical procedure. Once each procedure is complete, the shield is again extended and latched to provide a safety cover. A selectively activated unreleasible lock is also provided for the protective shield to assure secured needle tip protection at the end of use.

In one embodiment, the shield includes a needle guide proximally disposed relative to the tip of a needle, which protects the tip from damage through contact with the shield as the protective shield is displaced to cover and shield the needle and as the shield is removed to bare the needle for use. The needle guide is disposed and constrained to travel in alignment with the long axis of the needle and also constrained to facilitate movement of the shield about the needle without contact with the needle tip.

Generally, the device may be configured into at least two temporary or releasible but stable states. In one stable state the shield is constrained to be disposed "out-of-the-way" when the needle is bared for use. In a second releasible stable state, the shield is constrained to be protectively disposed about the needle and needle tip. Further, the device and shield, in combination, include the permanent lock which is securely and unreleasibly affixed to prevent further use of the device when use is complete. Preferably, latches are used to constrain the shield in each of the stable states.

Other important factors in safety needle devices involve whether the device can be effectively used by a single hand and the number of times a needle may be accessed while being maintained in a needle-safe condition between uses. Particularly in the case of hypodermic syringe needle devices, the ability to access a medical needle from a safety state a plurality of times is very important as it is common practice to prefill a syringe using a needle to access a medical fluid containing vial and then deliver the contents of the syringe to a patient using the same needle.

The invention generally provides for single-handed operation and for access to a medical needle a plurality of times while protecting a user from inadvertent injury from

the needle, and while protecting the needle and its fragile tip from damage when the device is moved to, displaced from or simply disposed within the safety of the shield.

Briefly summarized, the foregoing objects are achieved by a safety apparatus for reaccessibly shielding a medical needle, the apparatus comprising a medical needle assembly comprising a hollow bore cannula securely affixed in a hub and having a sharpened distally disposed tip to form the medical needle, a medical shield which is selectively displaced to an extended state to protectively cover the medical needle and deny access to the distally disposed tip for safety and is selectively displaced to a retracted state to permit access to the medical needle and sharpened tip for use in a medical procedure, a guide which is affixed relative to the shield and which is disposed about the cannula to assure, as the shield is displaced relative to the cannula, that the needle is directed into and out of being sheathed by the shield in such a manner that the needle tip is untouched by any part of the shield.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a medical needle shield assembly with a needle cover and a releasible needle shield.

Figure 2 is a perspective view of the medical needle shield assembly of Figure 1 with the needle cover removed.

Figure 3 is a perspective view of the medical needle shield assembly of Figure 2 with the shield partially displaced.

Figure 4 is a lateral cross section view of the medical needle shield assembly as seen in Figure 3.

Figure 5 is a perspective view of the medical needle shield assembly of Figure 3 with the shield fully displaced to protectively cover the needle.

Figure 6 is a lateral cross section view of the medical needle shield assembly as displaced in Figure 5.

Figure 7 is a perspective view of a medical needle shield assembly which is substantially the same as the assembly of Figure 2 except that this assembly is seen without a needle and with an unreleasible catch and latch.

Figure 8 is a lateral cross section view of the assembly shown in Figure 7 wherein a releasible catch and latch, that constrains the assembly in a stable folded state is shown.

DETAILED DESCRIPTION OF THE INVENTION

In this description, the term proximal is generally used to indicate relative nearness of a referenced item to a user of a device or a viewer of a perspective drawing of a figure. The term distal is similarly used to indicate relative remoteness. Reference is now made to the embodiments illustrated in Figures 1-8 wherein like numerals are used to designate like parts throughout. In those cases where parts have similar, but not identical, form and function, numerals with primes may be used for ease in interpretative cross referencing.

Reference is now made to Figures 1-6 wherein a basic embodiment of the instant invention is disclosed. As shown in Figure 1, this embodiment is a needle shielding safety device 10. Device 10 is seen to have a needle cover 20 and a needle-hub-shield assembly 30.

Assembly 30 is also illustrated in Figure 2 wherein cover 20 is shown to be removed to expose a medical needle 40 and otherwise concealed distal portions of a foldable needle shield 50. As is apparent from differences between Figures 1 and Figure 2, needle cover 20 has an elongated hollow frustoconical distal part 60, which is similar in form and function to needle covers commonly used for protecting needles prior to use. Cover 20 also has a laterally and proximally disposed guard 70. Guard 70 acts as a keeper against inadvertent unfolding or safety actuation of shield 50 before removal of cover 20 for use of needle 40. Similar to currently available needle covers, needle cover 20 may be formed (e.g., injection molded) from polypropylene, other synthetic resinous material, or equvalents thereof.

It is important to note that for devices which permit reaccessing a medical needle, a cover such as cover 20 may not be necessary. When a shield is securely, but releasibly latched, a device such as assembly 30 may be deployed in a safe state with a needle 40 being protectively covered by a shield, such as shield 50 in Figure 5. The device so deployed may then be packaged and shipped in an antiseptic protective wrap, such as a

"bubble pack" without a cover, such as cover 20. Such a deployment and elimination of a cover reduces both the cost of the basic device and the cost of discarding ancillary parts.

In addition to needle 40 and shield 50, assembly 30 has a needle hub 80 to which needle 40 is securely affixed and to which shield 50 is hingedly affixed. In this embodiment, hub 80 is seen to comprise a female luer fitting 90, though other flow through hub fitting and connections may be used within the scope of the instant invention. Needle 40 is generally formed from a hollow bore cannula to have an elongated shank 92 and a sharpened tip 100.

Primary to the inventive novelty of this embodiment is shield 50. As may be better seen in Figures 3 and 4, shield 50 is formed from two segments, a distal segment 110 and a proximal segment 120. It should be noted that more than two segments may be used to form a foldable needle shield.

Distal segment 110 is made to have a pair of juxtaposed elongated side pieces 122 and 124 and a closed end 126 which is formed to be contiguous with side pieces 122 and 124 and thereby form a hollow needle tip 100 guard recess 128. As shield 50 unfolds to protect needle 40 and needle tip 100, tip 100 should make no contact with any parts of distal segment 110. Such contact may jeopardize the structural integrity of tip 100 and, therefore, similarly jeopardize continuing use of needle 40. To assure that needle tip 100 is guided in and out of distal segment 110 in both cases where shield 50 is unfolded to become a shroud and refolded to bare needle tip 100 for further use, a yoke 130 is affixed to side members 122 and 124 by a pair of hinges 132 and 134, respectively (see Figure 2). Yoke 130 has a needle bearing surface 136 upon which needle 40 glides as distal segment 110 rotates about needle 40 during folding and unfolding. As seen in Figure 6, distal segment 110 has an arcuately formed guide 138 disposed to provide a convex guide surface 140 between needle 40 and needle bearing surface 136. In combination, yoke 130 and guide 138 act to deflect or lift needle 40 from guard recess 128 as shield 50 is folded and to guide needle 40 into guard recess 128 as shield is unfolded thereby protecting tip 100 from contact with shield 50. For these reasons, such combinations may be referenced as guides or bearings herein.

In addition, segment 110 has a pair of proximally disposed connective hinges 142 and 144 (see Figure 2) by which segment 110 is hingedly affixed to segment 120. It

should be noted that all or part of the hinges of assembly 30 may be formed as living hinges by injection molding all or any combination of parts of hub 80, proximal section 120 and distal section 110, if an appropriate material such as polypropylene is used.

Also proximally disposed is a medially aligned transverse bar 146 which has a sloped face 148 (see Figures 4 and 6). Sloped face 148 is so sloped to act as a catch for a latch disposed in proximal segment 120 and described in detail hereafter.

Referring now to Figures 2-5, proximal segment 120 is shown to comprise a pair of lateral sides 152 and 154 joined by a top piece 156. As may be seen in Figures 5 and 6, sides 122, 124, 152 and 154 cooperate to form a channel 157 which acts as a protective side guard for needle 40 and tip 100 when shield 50 is extended. Top piece 156 has a prominent button 158 superiorly disposed for easy digital access. Integral to button 158 is a distally extending arm 160, which terminates in an inwardly directed latch hook 162 (see Figure 6). Latch hook 162 has a proximally disposed latch face 164 (seen in Figure 4), which is disposed to interactively latch against a catch formed by sloped face 148 when shield 50 is completely unfolded.

Also, integral with button 158 is a proximally extending arm 166 (see Figures 4 and 6). Arm 166 is bent at an elbow 168 to terminate in an inwardly extending cross member 170. Cross member 170 is transversely, securely affixed to lateral sides 152 and 154 (see Figure 3) in a cantilevered fashion such that retractive force applied to button 158 causes arm 160 to rotate upwardly and outwardly relieving the catch formed at faces 148 and 164. This permits shield 50 to be folded and thereby lift needle 40 from confinement of shield 50 for use in a medical procedure.

As seen in Figure 5, proximal segment 120 is affixed to needle hub 80 by a pair of hinges 172 and 174 associated with lateral sides 152 and 154, respectively. Hinges 172 and 174 permit proximal segment 120 to rotate through an angle required to fold and unfold shield 50 about needle 40. As shield 50 folds and unfolds, distal segment 110 rotates about needle 40 in a manner dictated by the interface between yoke 130, needle 40 and arcuate guide surface 140. Yoke 130 is free to rotate by hinged attachment through hinges 132 and 134 (see Figures 3 and 5) as segment 110 rotates about needle 40. In doing so, yoke 130 remains in alignment with needle 40 and provides a lift and guide as the segment rotates. In this manner, needle tip 100 is untouched by any structure of

shield 50. The displacement of needle tip 100 under the control of yoke 136 and arcuate guide surface 140 is best seen in combination in Figures 4 and 6.

In Figure 5, shield 50 is fully unfolded and extended. A proximal and upward force placed upon button 158 causes shield 50 to unfold through the intermediate state seen in Figures 3 and 4, and further to a completely folded state seen in Figure 2. A distal and arcuately downward force placed upon button 158 causes shield 50 to be displaced from the state seen in Figure 2 through the state of Figures 3 and 4, and further to the unfolded state of Figure 5. In this manner, needle tip 100 may be alternately protected by shield 50 and removed from shield 50 for use a plurality of times, with needle tip 100 being fully protected by an unfolded shield 50 between medical procedures.

Following the last use of assembly 30 in a medical procedure, it is preferred that shield 50 be unreleasibly latched as a final precaution. An unreleasible latch or lock may be provided by a number of latching mechanisms within the scope of the instant invention disclosed herein. One such mechanism is seen as a part of assembly 30' in Figure 7. With the exception of the following disclosed variations, assembly 30' is similar to assembly 30, earlier described, and, in the same manner, shield 50' is similar to shield 50. Shield 50' has a top piece 156' with a button 158, and a protruding latch part extends toward a lateral side 152' of a proximal segment 120' (Lateral side 152' is not shown in the figures, but is similar to lateral side 152 of proximal segment 120 of assembly 30 and is referenced by the same number 152, with a prime.) Latch part 180 has the form of an arrow 182 having a pointed end 184 and a pair of juxtaposed ledges 186 and 188.

Juxtaposed to pointed end 184, lateral side 152' has a slot 190, partially closed by a pair of ears 192 and 194. Ears 192 and 194 are spaced apart just far enough to permit total entry of arrow or barb 182 into slot 190 by distortion of ledges 186 and 188. Once arrow 182 is so displaced into slot 190, the action of ears 192 and 194 against ledges 196 and 188, respectively, unreleasibly retain latch part 180 in slot 190. Such an unreleasible latch is accomplished by selectively applying a force upon button 158, which is sufficiently greater than the force to close and affix latch hook 162 of top piece 156' to a transverse bar 146 (see Figure 6).

It is also desirable to assure that shield 50' (and shield 50) is in a stable state when folded. Such assurance is achievable using a releasible latch as well as by friction. One

releasible latch is seen in Figure 8. In Figure 8, a laterally extending arm 166' of top piece 156' ends in a "j" section 200 having a sloping face which forms a latch 202. To form a catch for latch 202, hub 80' has an outward extending excrescence 210 to form a catch 212. Note, that, when assembly 30' is folded, latch 202 and catch 212 retain shield 50' in a stable, folded state. However, by placing sufficient distally directed force upon button 158, arm 210' is deflected to release latch 202 from catch 212 permitting shield 50' to unfold and protectively cover needle 40 and needle tip 100.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiment is therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

CLAIMS

1. A safety apparatus for reaccessibly shielding a medical needle, said apparatus comprising:

a medical needle assembly comprising a hollow bore cannula securely affixed in a hub and having a sharpened distally disposed tip to form the medical needle;

a medical shield which is selectively displaced to an extended state to protectively cover the medical needle and deny access to the distally disposed tip for safety and is selectively displaced to a retracted state to permit access to the medical needle and sharpened tip for use in a medical procedure; and

a guide which is affixed relative to the shield and which is disposed about the cannula to assure, as the shield is displaced relative to the cannula, that the needle is directed into and out of being sheathed by said shield in such a manner that the needle tip is untouched by any part of the shield.

2. The safety apparatus according to Claim 1, further comprising a selectively actuated unreleasible latch and catch apparatus whereby said shield is unreleasibly affixed to said cannula to deny any further access to said needle and sharpened tip.

3. The safety apparatus according to Claim 1, wherein said shield comprises a segment which encloses said sharpened tip, the segment comprising a channel which is closed distal from the hub.

4. The safety apparatus according to Claim 1, wherein said shield and said hub, in combination, comprise a releasible latch and catch mechanism which keeps the shield, when retracted, in a stable but selectively releasible state.

5. The safety apparatus according to Claim 1, wherein said shield is made as a single, integral molded part.

6. The safety apparatus according to Claim 1, wherein said shield comprises a hinge by which said shield is joined to said hub.

7. The safety apparatus according to Claim 1, wherein said shield comprises a plurality of serially interconnected substantially rigid segments each of which is interconnected to at least one adjacent segment by an intersegment hinge, at least one segment comprising an open orifice, through which said cannula passes to form an axis of intersection about the cannula, and a channel along which the cannula is disposed when the shield is linearly extended, said shield and said hinges being disposed to permit usable access to said sharpened tip in a medical procedure and extending of the shield to a substantially planar disposition along said cannula whereat the cannula is disposed along the channel without said sharpened tip coming in contact with any portion of said shield.

8. The safety apparatus according to Claim 7, wherein said shield further comprises at least one releasible latching member which affixes the shield relative to the cannula, said shield and cannula, in combination, thereby forming a substantially rigid body which protectively encloses and denies access to said sharpened tip unless and until said releasible latching member is selectively actuated to permit refolding said shield and allowing reaccess to said needle and sharpened tip.

9. The safety apparatus according to Claim 7, further comprising a selectively actuated unreleasible latch and catch apparatus whereby said shield is unreleasibly affixed to said cannula to deny any further access to said needle and sharpened tip.

10. The safety apparatus according to Claim 7, wherein said shield and said hub, in combination, comprise a releasible latch and catch mechanism which keeps the shield, when folded, in a stable but selectively releasible state.

11. A method for enclosing and reaccessing a sharpened medical needle comprising the steps of:

(a) providing a safety apparatus for shielding the medical needle, said apparatus comprising a hollow bore cannula securely affixed in a hub and having at least one sharpened tip to form the medical needle and a part hingedly joined to said hub, said part comprising an elongated shield which comprises a plurality of serially interconnected substantially rigid segments each of which is interconnected to at least one adjacent segment by an intersegment hinge, at least one segment comprising an open orifice, through which said cannula passes to form an axis of intersection about the cannula, and a channel along which the cannula is disposed when the shield is linearly extended, said shield and said hinges being disposed to permit usable access to said sharpened tip in a medical procedure and extending of the shield to a substantially planar disposition along said cannula whereat the cannula is disposed along the channel, said shield further comprising at least one releasible latching member which affixes the shield relative to the cannula, said shield and cannula, in combination, thereby forming a substantially rigid body which protectively encloses, without any portion of said shield contacting said sharpened tip, and denies access to said sharpened tip unless and until said releasible latching member is selectively actuated to permit refolding said shield and allowing reaccess to said needle and sharpened tip;

(b) displacing said shield about said hub and cannula into a compact, folded state such that said needle tip is accessible for a medical procedure;

(c) at the end of a phase of said medical procedure unfolding and extending the shield about the needle and selectively actuating the releasible latching member; and

(d) reaccessing the needle by selectively releasing the releasible latching member and refolding the shield to the folded state.

12. The method for enclosing and reaccessing a sharpened medical needle according to Claim 11, comprising an additional step (c).

13. The method for enclosing and reaccessing a sharpened medical needle according to Claim 11, comprising an additional step (d).

14. The method for enclosing and reaccessing a sharpened medical needle according to Claim 11, comprising additional steps of providing an unreleasible latch/catch mechanism.

15. The method for enclosing and reaccessing a sharpened medical needle according to Claim 14, comprising an additional step of selectively activating the unreleasible latch/catch mechanism thereby disallowing further use of the needle and needle tip.

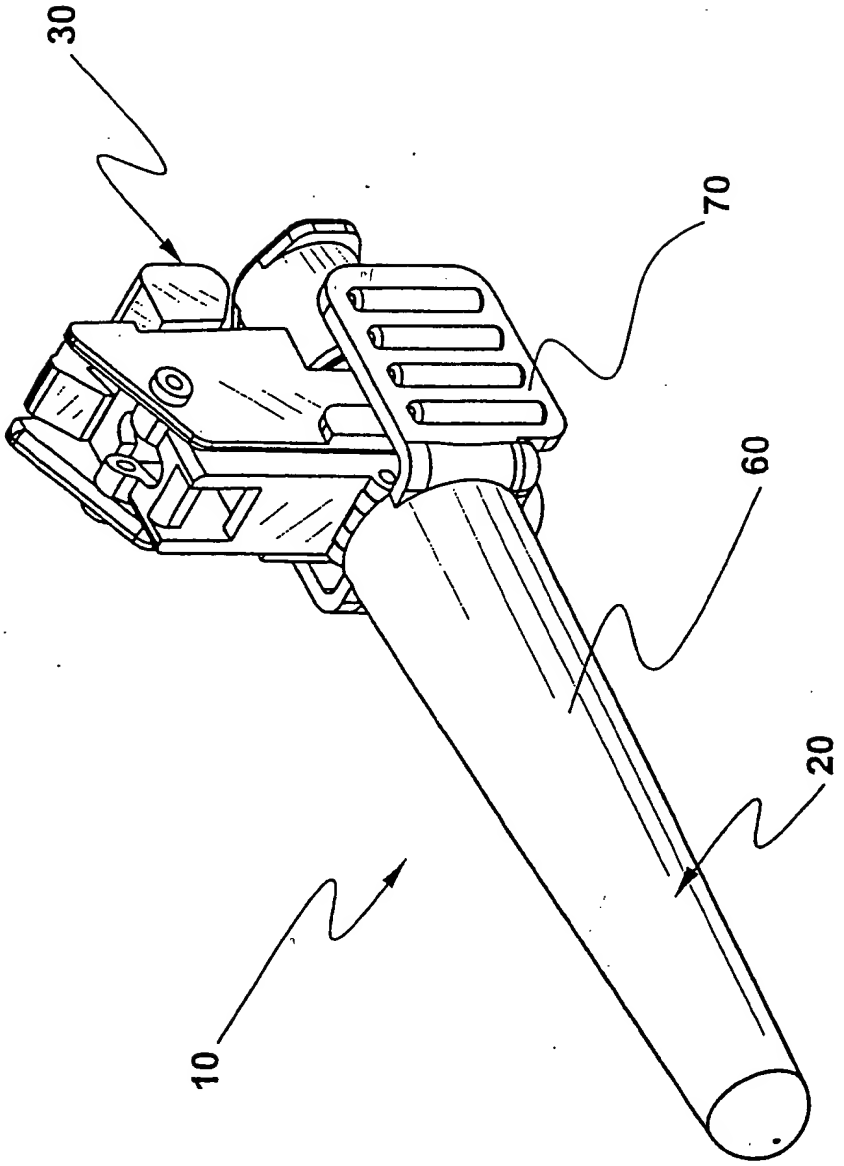

FIGURE 1

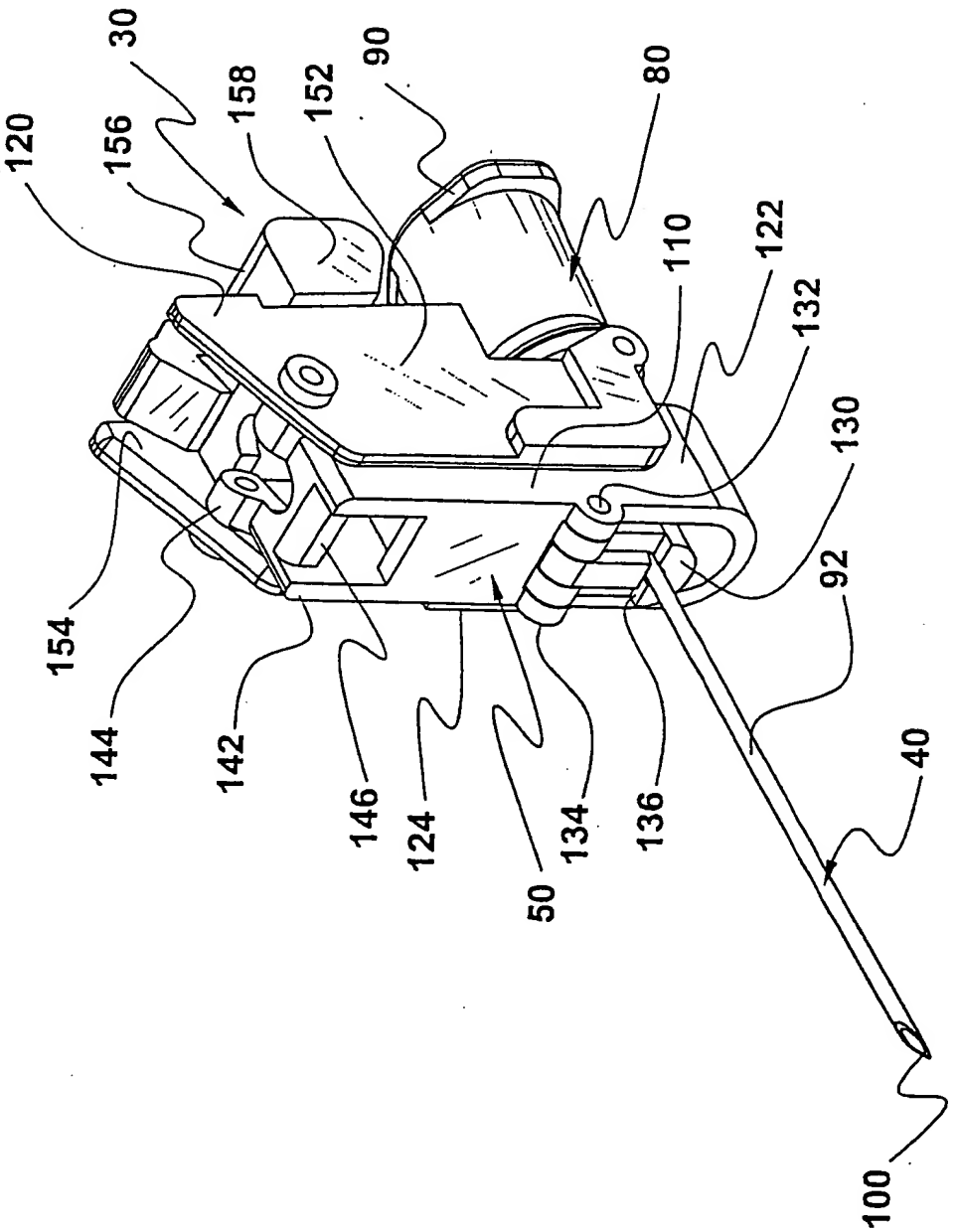
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FIGURE 2

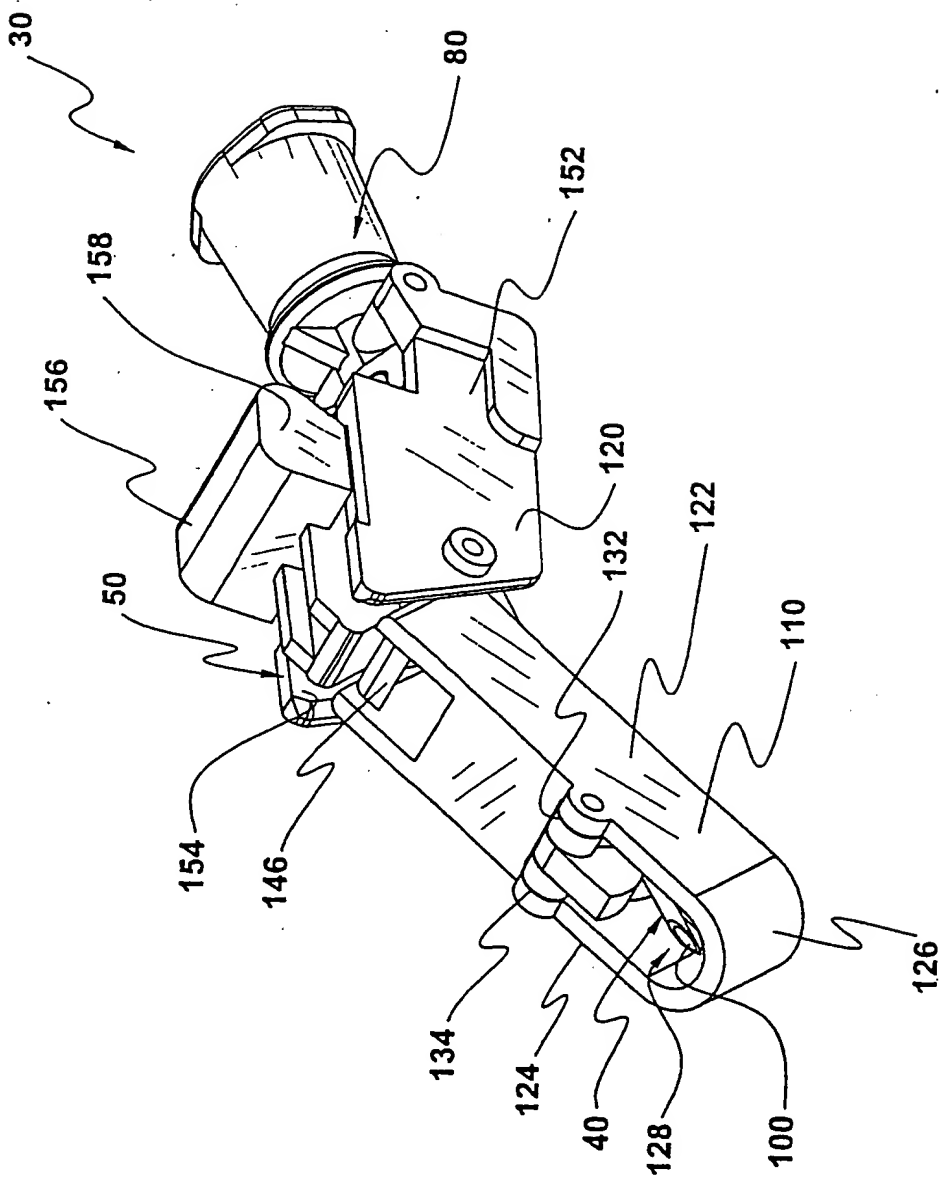
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FIGURE 3

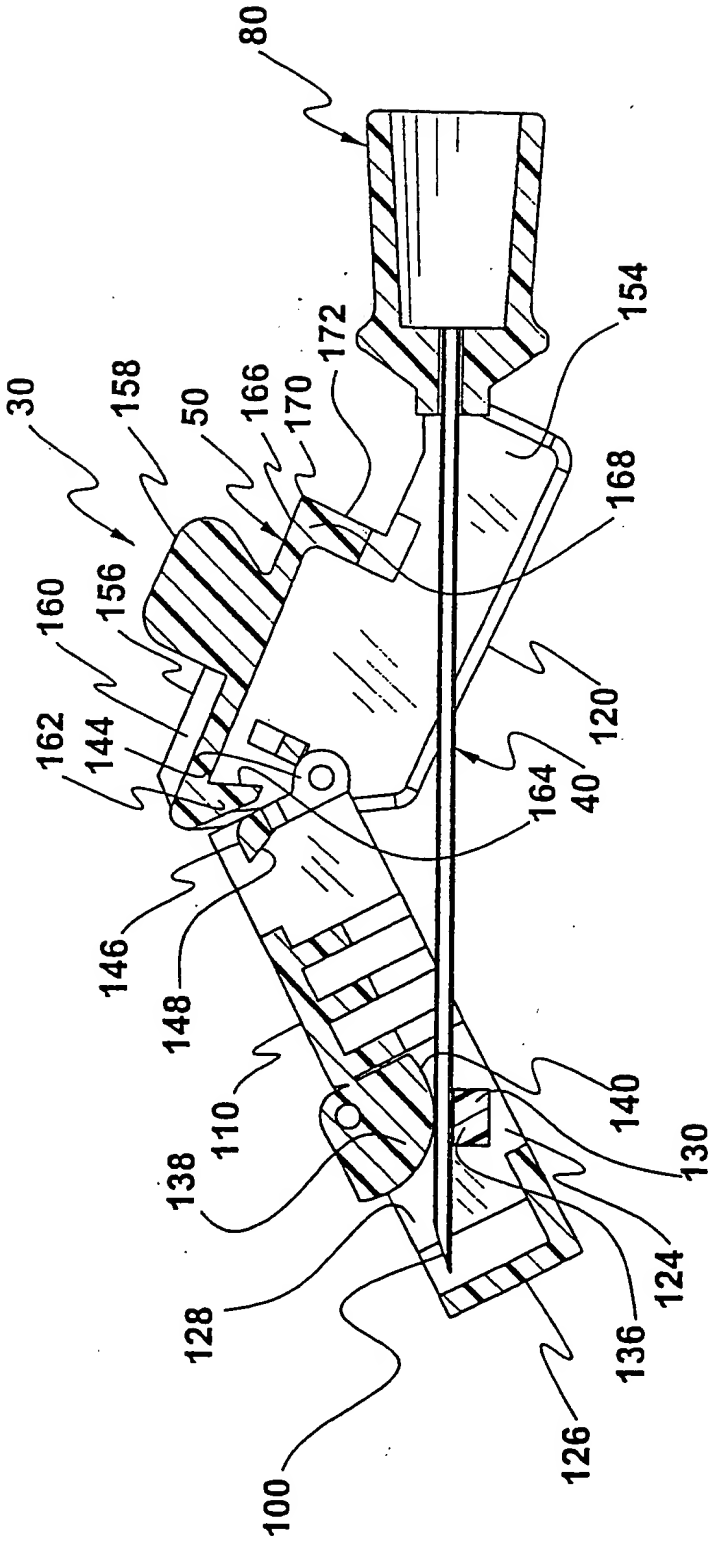
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FIGURE 4

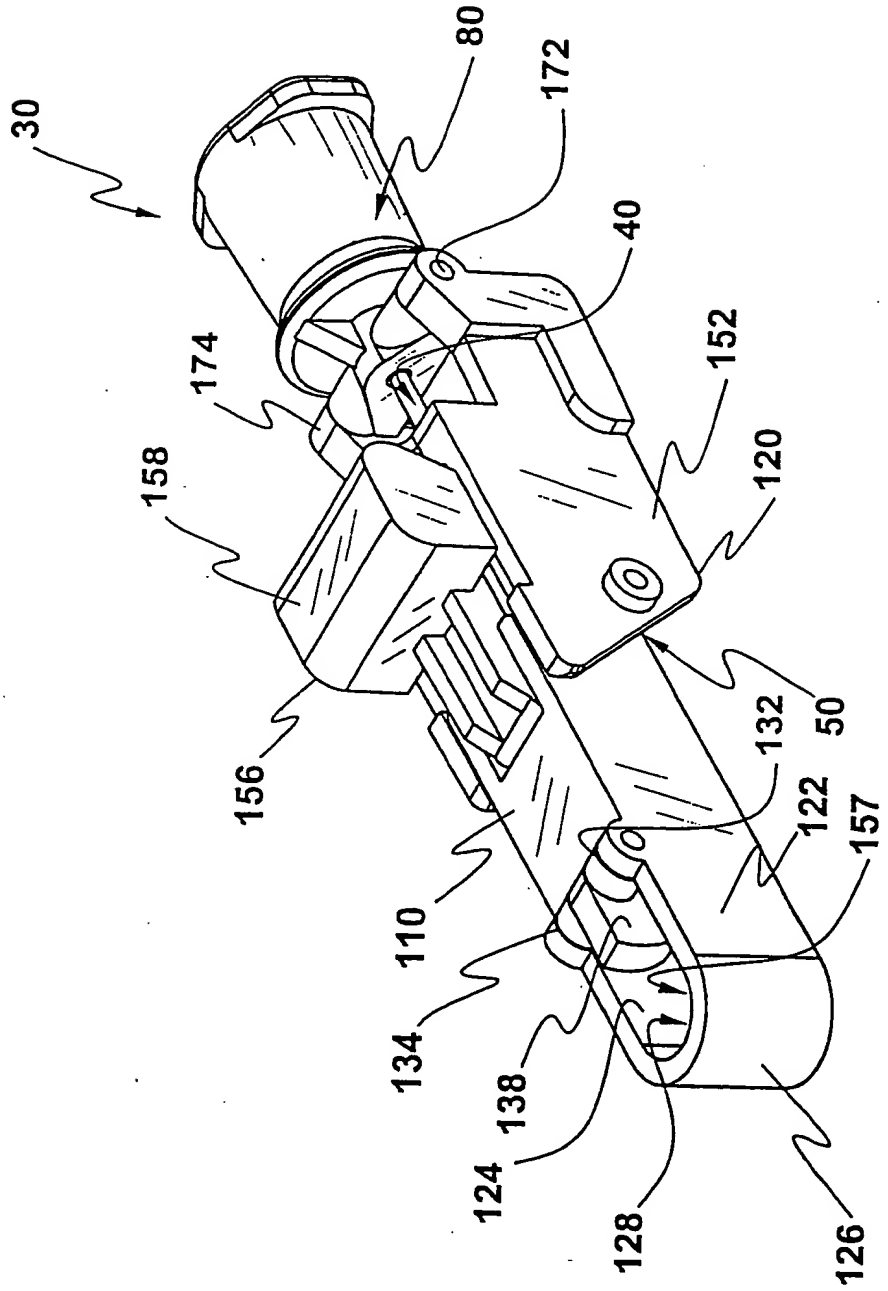
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FIGURE 5

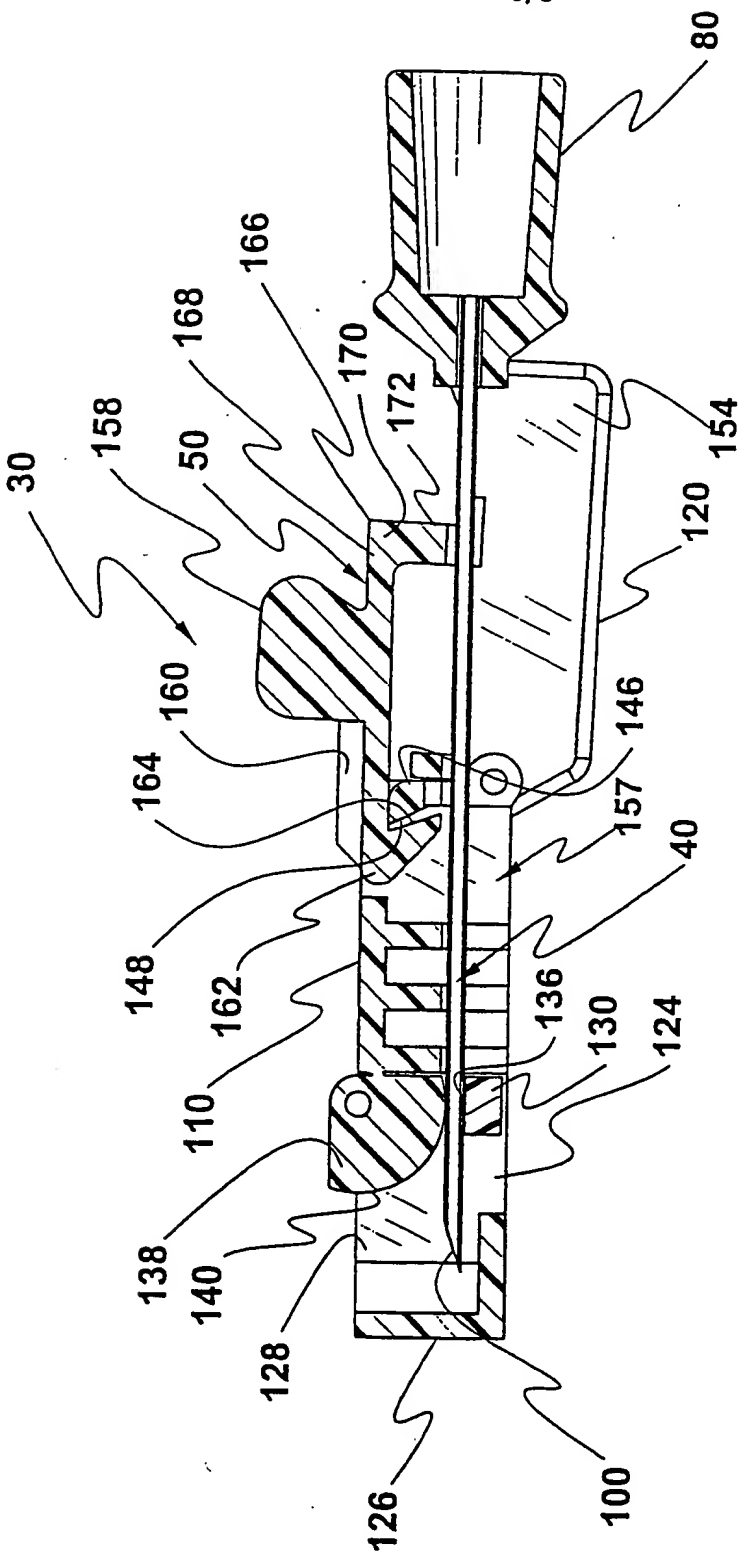
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FIGURE 6

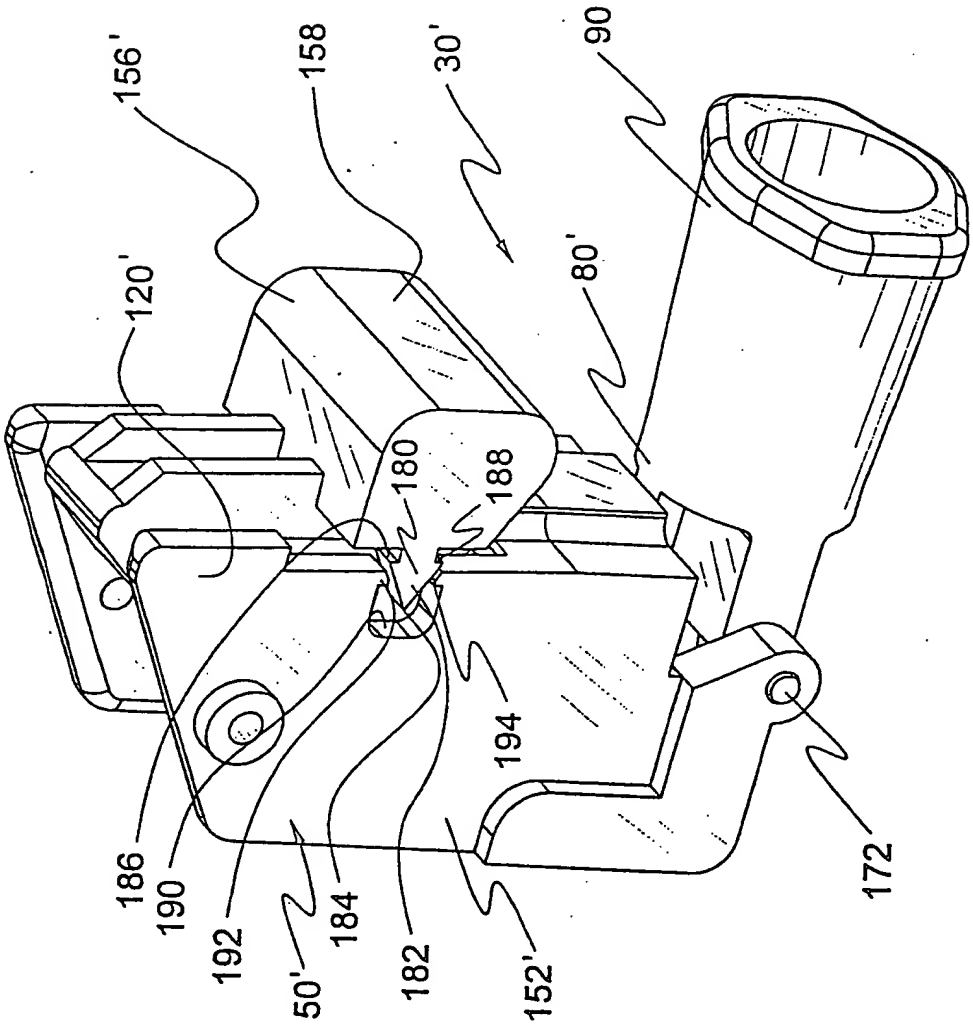

FIGURE 7

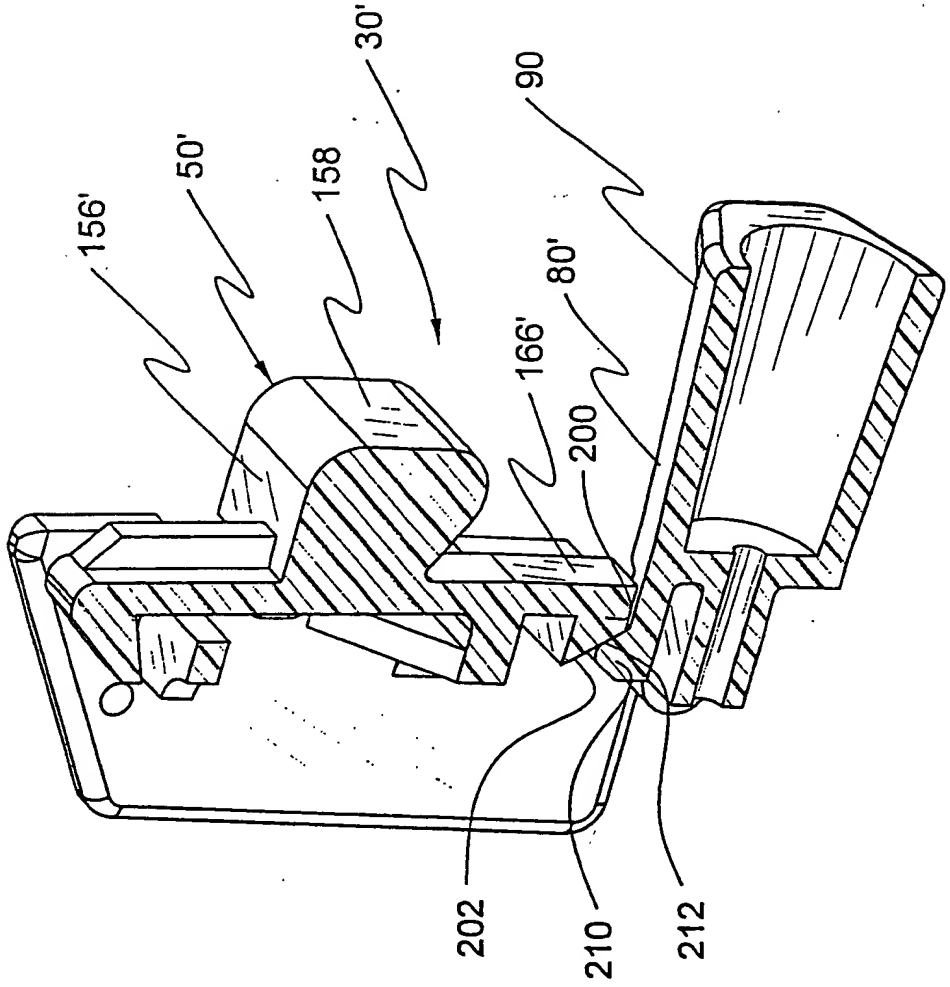

FIGURE 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/29998

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/00
US CL : 604/263

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/263,264,268,272,187,192,198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,935,013 A (Haber et al.) 19 June 1990, see entire document.	1,3-8,10
Y		2,9,11-15
X	US 5,957,892 A (Thorne) 28 September 1999, see entire document.	1,6-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
16 JANUARY 2001	26 FEB 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CATHERINE SERKE Telephone No. (703) 308-4846

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